Acquisition & Assistance Policy Directive (AAPD)

From the Director, Office of Acquisition & Assistance Issued: February 10, 2005

AAPD 05-01

Procurement of HIV-AIDS Test Kits from Code 935 Countries

Subject Category: Assistance, Acquisition Management
Type: Policy and Procedure

AAPDs provide information of significance to all agency personnel and partners involved in the Acquisition and Assistance process. Information includes (but is not limited to): advance notification of changes in acquisition or assistance regulations; reminders; procedures; and general information. Also, AAPDs may be used to implement new requirements on short-notice, pending formal amendment of acquisition or assistance regulations.

AAPDs are EFFECTIVE AS OF THE ISSUED DATE unless otherwise noted in the guidance below; the directives remain in effect until this office issues a notice of cancellation.

This AAPD: ☐ Is New ☐ Replaces/ ☒ Amends CIB/AAPD No: 01-04

Applicable to:	Precedes change to:
☒ Existing awards; ☐ Modification required	☐ AIDAR Part(s) Appendix
☐ No later than	☒ USAID Automated Directives System (ADS) Chapters 302, 303
☐ As noted in guidance below	☐ Code of Federal Regulations
☒ RFPs/RFAs issued on or after the effective date of this AAPD; all other Pending Awards, i.e., 8(a), sole source, IQC	☐ Other
☐ Other or N/A	☐ No change to regulations

☐ New Provision/Clause Provided Herein: If checked, scheduled update to Prodoc:

(signed copy on file)

Kimberly Triplett, Acting Director

AAPD 05-01 -- Procurement of HIV-AIDS Test Kits from Code 935 Countries

PURPOSE: The purpose of this AAPD is to update the list of Testing Kits included in Contract Information Bulletin (CIB) 01-04 that were approved for purchase for HIV/AIDS programs from Geographic Code 935 countries (any country or area excluding foreign policy restricted countries). The updated list is included in the GUIDANCE section below and may be revised and updated yearly or as necessary by the Office of HIV/AIDS (OHA), Bureau for Global Health, with the approval of AA/M, and issued through an amendment to this AAPD.

BACKGROUND: On January 11, 2001, the Administrator of USAID authorized the procurement of certain listed test kits from Geographic Code 935 countries. Test kits eligible for this procurement were listed in Tab 1 to that waiver. The waiver also delegated authority to AA/M to amend the list at Tab 1 to the waiver, to add new testing kits which could be determined to meet the same criteria. This waiver was included in CIB 01-04.

GUIDANCE:

a. Procurement in Geographic Code 935 countries is authorized for the test kits listed below.

Approved List of Testing Kit Products and Manufacturers as of February 15, 2005

Product	Source Country	Manufacturer
Bioline	South Korea	Standard Diagnostics
Bionor	Norway	Bionor A/S
Capillus	Ireland	Trinity Biotech*
Determine	Japan	Abbott Laboratories*
DoubleCheck	Israel	Orgenics
First Response	India	Premier Medical Corporation
Genie II	France	BioRad
Hema-Strip	Singapore	Saliva Diagnostic Systems, Ltd.*
HIVSav 1&2	Israel	Sayvon Diagnostics Ltd.
Immunocomb	Israel	Orgenics
Instant Screen	Germany	GAIFAR GmbH
InstantCHEK	USA	EY Laboratories
OraQuick	Singapore	OraSure Technologies
SeroCard	Ireland	Trinity Biotech*
Sero-Strip	Israel	Saliva Diagnostic Systems, Ltd.*
Stat-Pack	USA	ChemBio Diagnostics, Inc.
SureCheck HIV	USA	ChemBio Diagnostics, Inc.
Unigold	Ireland	Trinity Biotech
* Parent Company is a United States based firm		

b. Choosing test kits for country programs

While purchase of kits on the approved list is authorized, different kits are appropriate for different countries and testing situations. We recommend that kits be evaluated in country for their performance as part of a national testing algorithm. Guidance on HIV rapid test kit evaluation is available at http://www.phppo.cdc.gov/dls/pdf/HIV%20Test%20Guidelines%20Africa.pdf .

c. Adding additional test kits to the list

For an HIV/AIDS test kit to be added to the list of those approved for procurement from Geographic Code 935 countries, the following information regarding such test kit must be submitted to OHA:

1. Whether it has FDA-approval:
2. Whether its producer has FDA-approval;
3. Whether the facility and production site where it is manufactured has FDA-approval;
4. Whether the test kit, producer, or production site has approval of a stringent regulatory authority[1]; and
5. Why the proposed test kit is necessary and appropriate for the country/countries concerned.

Alternatively, OHA will accept notification from the Department of Health and Human Services Centers for Disease Control and Prevention ("CDC") that they have evaluated the test kit and find that it meets the attached criteria.

Attachment**:** RAPID HIV TEST KIT TECHNICAL REQUIREMENTS

[1] A stringent regulatory authority is a drug regulatory body that closely resembles FDA in standards utilized in its operations. Currently, countries that participate in the International Conference on Harmonization (ICH) are considered as stringent regulatory authorities. The ICH regulatory bodies include: the U.S. FDA; the Japanese Ministry of Health, Labor, and Welfare; the European Agency for the Evaluation of Medicinal Products (EMEA) centralized procedure; and the European Free Trade Area (represented by the Swiss Medic). The Canadian drug regulatory authority, the Therapeutic Products Directorate, Health Canada, is an observer to the ICH and is also considered a stringent regulatory authority. Other countries may be considered having a stringent regulatory body if they have implemented ICH guidelines and resemble the U.S. FDA in operation, but would be considered on a case-by-case basis. It should be noted that the World Health Organization (WHO) has a pre-qualification program for procurement purposes. The WHO is not a regulatory authority, and acceptance of a manufacturer or product by the WHO pre-qualification program would not be considered equivalent to approval of a product by a stringent regulatory authority.

POINT OF CONTACT: Please direct any questions pertaining to the test kits to Katharine Kripke, GH/OHA/TLR, Phone: (202) 712-1452, e-mail: kkripke@usaid.gov. Please direct questions about the AAPD to Diane Howard, M/OAA/P, Phone (202) 712-0206.

Attachment to AAPD 05-01 -- Procurement of HIV-AIDS Test Kits from Code 935 Countries

RAPID HIV TEST KIT TECHNICAL REQUIREMENTS

1. HIV Rapid Test Kits:

   HIV rapid tests are defined as assays for detection of antibodies to HIV-1, HIV-2, or both, from which test results can be read directly, within 30 minutes of the time specimen is applied to the device, without calibration, interpretation, or calculations. Qualifications for HIV rapid test kits are listed below. The only acceptable kits are those meeting the test characteristics described below. Acceptable kits may change periodically as evaluation data on kit performance is updated.

   A. Test Characteristics:

      i. Documentation from manufacturer studies that test has sensitivity of at least 99% and specificity of at least 98% for detection of HIV-1 in each sample matrix for which the test is designed (e.g., whole blood, serum, plasma, oral fluid or urine). Data should be based on at least 500 HIV negative and 500 HIV-1 positive specimens. If test claims to detect both HIV-1 and HIV-2, sensitivity for HIV-2 should be demonstrated with evaluation of 50 HIV-2 positive specimens, and must be at least 99%.

      ii. One or more credible evaluations by internationally recognized independent institutions validating that sensitivity and specificity of the tests are within 95% +/- 2% confidence interval of that demonstrated in manufacturer's studies (criterion i.). Approximately 200 HIV-positive and 200 HIV-negative specimens are needed to provide 95% confidence intervals of less than ± 2% for both the estimated sensitivity and specificity. A document that describes the process of such an evaluation can be found at:

      http://www.phppo.cdc.gov/dls/pdf/HIV%20Test%20Guidelines%20Africa.pdf

      iii. Presence of a normal internal control or other failure alert mechanism to notify the operator if the assay malfunctions. Also, having external controls that assure the presence of functional test antigens in the test platform will be very useful.

   B. Performance Characteristics:

      1). Use direct, unprocessed specimens (e.g., unprocessed whole blood or oral fluid) or samples that require minimal processing (e.g., serum or plasma).

      2). All reagents including diluents are included in kit, and require no technique-dependent reagent manipulation (e.g., no reconstitution)

      3). No operator intervention or procedural steps during the analysis after initial addition of specimen and reagents.

      4). No requirements for assay-specific equipment.

      5). Kits and all reagents stored at temperatures recommended by manufacturers shall have a minimum 1-year shelf life when received by contractors.

C. Manufacturing Characteristics:

The HIV rapid test kits must be purchased from manufacturers of those kits that meet the test characteristics and performance characteristics, described in sections A. and B., and manufacturing characteristics described below. As the list of tests is updated, the eligible manufacturers may change.

Eligible manufacturers must have:

i. Documented production capacity to provide the number of kits needed by USG programs for current and projected assay usage (e.g., 200,000 – 500,000 test kits needed annually), and ability to deliver a minimum of 45,000 test kits within 90 days of order.

ii. Availability of data to document reproducible performance across different lots of assay.

iii. Ability to ship to international sites.

iv. Documentation of export certificate, when required.